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TITLE: Study of Prostate Cancer Screening and Mortality in Black and White Men in the
Five Atlanta Area SEER Counties

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14. ABSTRACT We are implementing a case-control study of prostate cancer screening and mortality in 5 Metro Atlanta & 23 North Central Florida counties to determine if screening with the PSA/DRE reduces mortality from prostate cancer in black and white men. 566 Prostate cancer deaths (221 Black and 345 Whites Men) occurring to residents of Metro Atlanta during 1998-2001 were identified, reviewed, and linked to the hospital(s) of prior treatment. IRB approval and access to medical records have been requested from most of the institutions and IRBs. A total of 436 charts have been reviewed to date. Majority of the charts were obtained from the 5 largest hospitals in Atlanta: Crawford Long, Dekalb Med Ctr., Emory Univ Hospt, Grady, and Piedmont Hospital. Efforts are underway to obtain information from hospital-based controls in Atlanta. Three locations in north central Florida: VA Medical Center, Shands at U of Florida and Shands Jacksonville will provide access to prostate cancer patient records starting March 2006 to determine cases from the 23 participating counties. Post-Doctoral fellow Dr. William MKanta (01/13/06 -) and Research Assistant (Spring 2006) have been hired to manage the project and collect data in Florida. Activities for the current period include (1) identification of controls in Atlanta, (2) chart reviews for prostate cancer deaths in Atlanta & Florida, & (3) preparation of preliminary data analysis from the charts of cases reviewed.					
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Study of Prostate Cancer Screening and Mortality in Black and White Men in the Five Atlanta SEER and Twenty Three North Central Florida Counties

I. Introduction

Prostate cancer is the leading cause of cancer morbidity and the second leading cause of cancer mortality among U.S. men, and is projected to account for an estimated 232,090 new cases and 30,350 deaths in the year 2005. The significant changes in incidence and mortality that occurred since 1988 (significant rise between 1988-92, decreased between 1992-95, and increase between 1995-2004 in men <65 years of age, have been attributed to increased awareness of the disease and efforts at early diagnosis with the Prostate-Specific Antigen (PSA). African American men have the highest incidence and mortality rates in the world and continue to experience significantly higher incidence and twice as high death rates as whites in the U.S. The disparity in morbidity and mortality between African American men in the U.S. has not been adequately studied or explained, although it is generally believed that a number of factors are responsible, including stage at diagnosis and accessibility to health care (American Cancer Society Facts and Figures, 2005).

There is a great deal of controversy surrounding the interpretation of existing epidemiological and clinical evidence. Expert recommendations regarding the age, frequency and the necessity for the use of the Prostate Specific Antigen (PSA) and the Digital Rectal Examination (DRE) for mass screening in the general population as a public health policy remain conflicting and controversial. Results from large scale randomized controlled trials conducted by the National Cancer Institute and the European Union, necessary to document the benefits of screening through reduction in mortality, will be available in few years. Meanwhile, a number of case-control studies, including the present study, are underway to determine if screening with the PSA and DRE reduce mortality from prostate cancer.

II. Body

Objectives/Hypothesis: The objective of this study is to provide much needed data on the efficacy of screening for prostate cancer using observational case-control methodology while awaiting the results of randomized controlled trials and to explain the black white disparity in mortality from prostate cancer. The hypothesis to be tested is that the frequency of screening tests (DRE and PSA) should be higher in the general population than in the group of men who die from prostate cancer.

Specific Aim: Is to determine if screening with PSA and DRE reduces prostate cancer mortality.

Study Design: To accomplish this aim and test the hypothesis, a case-control study is being implemented in the 5 SEER Atlanta, Georgia and 23 North Central Florida counties with access to or with an automated linkage to death certificates. The frequency of PSA and DRE screening prior to the diagnosis of prostate cancer will be compared between a sample of 450 men (170 black & 280 white) who died/will die of prostate cancer in the 5 counties during the 4 year 1998-2001 period and a sample of 450 control men (170 black & 280 white) (sample size with adequate power) who did not die from prostate cancer. Deaths will be ascertained directly from the SEER Registry in Atlanta and the State Cancer Registry in Florida as well as the Georgia and Florida Departments of Public Health. The cases and controls will be frequency matched by race, age, sex and county of residence. Given the long and poorly understood natural history of prostate cancer, the favorable five-year relative survival rates for early stage disease, the advent of PSA utilization (1986), and to allow for the longer possible retrospective assessment interval of exposure data

from date of diagnosis, the prostate cancer deaths during 1998-2000 (2001 added if needed) will be included as cases. Death records will be systematically linked to hospital records using seven identifiers: name, social security #, date of birth or age, date of death, race and county of death and residence. Linkage and review of hospital records will be limited to the following hospitals in Atlanta: Grady Health System, Emory Hospitals, Piedmont Hospital, Crawford Long, Dekalb Medical Center, and V.A. Hospital, and in Florida to Shands Hospital and the North Florida South Georgia V.A. Medical Center. Hospital, physician and laboratory records will be reviewed to assess the frequency of DRE and PSA tests in cases and controls for a period of 12 to 14 years prior to the date of death of the case and to include the exposure period prior to the reference date of diagnosis of the case. The odds ratio with 95% C.I. will be used for overall comparisons and within subgroups defined by risk factors and adjusted for co-morbidity. Logistic regression will be used to generate summary odds ratios adjusted for co-variables.

III. Key Research Accomplishments

Key research accomplishments are based on progress made relative to each of the items listed under Task 1-5 in the Statement of Work that follows and submitted as part of the revised Proposal.

Statement of Work

Task 1. Personnel Recruitment/Arrangements

a. Prepare paper work, position description and advertisement.

Completed for both Atlanta and Florida Sites.

b. Hire and train data abstractor(s) at Morehouse School of Medicine and the University of Florida.

The hiring of personnel was completed at Morehouse School of Medicine from the inception of the Project. Yassa Nadjakani, MD, MPH has been associated with the project since the beginning (10/1/2001) although funding was not available for a considerable period of time during the transfer of the Project from MSM to UF. He continues to the present to be the Project Coordinator for the Atlanta area. We have hired new personnel in Florida - William Mkanta, PhD and Nicole Scheys, BS. Dr. Mkanta is the coordinator of the project. He is involved in the day-to-day administration of the project. He is responsible for establishing and maintaining contacts with hospital administration at Shands at the University of Florida, Shands Jacksonville, and VA hospitals. He is also involved in data abstraction, data analysis and IRB issues related to the project. Miss Scheys is responsible in record keeping, chart reviews, and preparation of reports. She also assists in patient interview in the Kidney Project whose PI is Dr. Asal.

c. Finalize arrangements with the Tumor Registries, the Health Departments, Hospitals, Laboratories, Urologists, and Primary Care Providers in Georgia and Florida.

Arrangements have been made with the Tumor Registries at the Georgia Department of Health and at the Florida Department of Health as well as the Offices of Vital Statistics in both Health Departments. Mortality records in the form of listings by year have been provided for prostate cancer deaths during 1988-2001. Approval from the Georgia Department of health and the SEER Registry in Atlanta has been received.

Approval has been received from all of the University/Hospital IRBs in both Florida and Atlanta. Consent Forms with HIPAA language approved by the Army IRB has been forwarded to each of the hospital IRBs in Florida and Atlanta. (Work in progress). Several of the hospitals have provided approval by a stamp on the Consent Form. Once received the approved consent forms will be forwarded to the Army IRB for final approval.

It is too early to begin contact with laboratories, urologists, and primary care providers. This process will begin once all cases have been identified; the records abstracted, controls identified through a match,

d. Obtain death certificate lists and all other materials from the State Health Departments and Tumor Registries in Atlanta and Florida.

This task has been completed.

Task 2. Sample Size Determination and Power Calculations, Months 1-4:

- a. Review Georgia/Florida State Departments of Health mortality records and Registry data for **1998-2000 (2001)** to determine the number of men dying from prostate cancer.

This activity has been completed. See tables 1 and 2 below.

- b. Determine the adequacy of sample size projected in the proposal.

The following Tables (1 and 2) summarize the prostate cancer mortality data obtained from the Georgia and Florida Departments of Health (Georgia Department of Human Resources/Georgia Cancer Registry).

Table 1: Prostrate Cancer Mortality in the 5 Metro Atlanta SEER Counties 1998-2001 By Race

County	1998 Black White		1999 Black White		2000 Black White		2001 Black White		Total Black White		Grand Total
Clayton	4	11	4	1	1	4			9	16	25
Cobb	3	33	6	21	5	26			14	80	94
Dekalb	24	32	17	22	17	27			58	81	139
Fulton	58	33	57	45	19	20			134	98	223
Gwinnett	1	23	3	26	2	21			6	70	76
Total	90	132	87	115	44	98			221	345	566

Table 2: Prostate Cancer Mortality in 23 North Central Florida Counties by Race 1998-2001

County	White Male Cases				Black Male Cases			
	1998	1999	2000	2001	1998	1999	2000	2001
St. Johns	16	14	9	17	0	1	2	2
Nassau	2	7	4	5	1	3	2	1
Duval	53	73	58	52	32	36	24	27
Clay	15	9	15	14	1	3	1	1
Baker	1	2	0	2	0	1	0	1
Flagler	11	10	11	6	4	1	3	1
Volusia	71	73	84	69	7	6	11	9
CHPA4 Jacksonville	169	188	181	165	45	51	43	42
Putnam	12	9	3	9	4	4	2	6
Alachua	17	16	16	11	8	5	8	7
Hamilton	0	0	2	1	4	0	0	1
Columbia	10	8	4	2	1	2	3	3
Union	2	1	0	3	0	1	0	3
Dixie	1	3	2	0	0	0	0	0
Lafayette	0	0	0	1	0	0	0	0
Suwannee	4	4	4	3	5	4	0	1
Marion	70	52	47	45	5	6	6	7
Sumter	5	7	6	0	1	3	0	0
CHPH3 Gainesville	121	100	84	75	28	25	19	28
Pasco	73	66	55		1	0	0	
Pinellas	132	144	134		8	12	11	
Tampa St.Petersbug, Clearwater	205	210	189		9	12	11	
Orange	60	61	52		20	16	30	
Seminole	28	26	32		11	2	4	
Osceola	11	16	13		2	2	3	
Orlando/other	99	113	97		33	20	37	
Tallahassee/Leon	17	14	18		11	7	11	
Total per Year	307	302	283		83	84	73	
Four Year Total	967+				268+			

The number of deaths recorded between blacks and whites Shown in Tables 1 and 2 above for the years 1998-2001 in Atlanta and Florida sites exceed the needed sample of 170 black and 280 white patients project as a minimum sample that will attain adequate power. The sample will be randomly selected from the list of patients making the prostate cancer mortality figures in Tables 1 and 2.

Task 3. Modify and Pre-test Medical Record Review Form

a. Modify, pre-test, refine, and finalize the medical record review forms.

Forms have been modified, pre-tested, finalized, used, and continue to be used in both Atlanta and Florida.

Telephone screening forms to select controls have been modified, approved by the Army IRB, and ready to be used to select controls.

b. IRB packages will include the final medical record review forms and protocol with sampling and data collection strategies and final sample size estimates.

Since receiving the tentative approval from the Army on April 1, 2005, final approval of the protocol and IRB Consent forms from each of the participating hospitals in Atlanta and North Central Florida.

Task 4. Access Hospital Lists/Select Controls:

a. Identify list of hospitals where cases were diagnosed in Georgia and Florida

Completed for Atlanta, but in initial stages in Florida.

b. Finalize arrangements with Florida hospitals for in-site visit

Visits have been made to the VA hospital, Shands at University of Florida, and Shands Jacksonville. Efforts are underway to start matching death records to identify cases that were treated at these facilities.

c. Selection of Controls at each hospital in Georgia and Florida.

Following completion of chart review for cases in Georgia, efforts are now directed to the selection of controls. This is not yet applicable in Florida.

Task 5. Conduct Medical Record Review/Computerize Data Set for Analysis.

a. Begin Data collection on cases and controls from hospitals, clinics, physicians and laboratories.

A total of 436 charts (176 blacks, 260 whites) have been identified in the Atlanta area hospitals (Appendix A). Efforts are underway to identify cases in Florida. Requests have been submitted to the VA hospital, Shands at UF, and Shands Jacksonville.

b. Conduct the medical record review on 450 black and white male prostate cancer deceased cases and their 450 frequency matched age and race male controls.

A total of 436 (176 blacks, 260 whites) charts have been reviewed by January 2006. All these charts are from the Atlanta site.

b. Ongoing quality control, cleaning, and completeness of data.

This process goes on for the records reviewed from the Atlanta site.

c. Computerize completed, cleaned, and validated data and translate into ASCII file format with a data dictionary.

Not Applicable For This Report

Task 6. Data Analysis.

a. Comprehensive analyses of collected data according to the statistical procedures outlined in the statistical section of the proposal.

Not Applicable For This Report

Task 7. Final Report/Manuscript Preparation.

a. Preparation of the final report to funding agency and manuscript prepared for publication.

Not Applicable For This Report

IV. Reportable Outcomes.

Completion of chart reviews for cases at the Atlanta site.

V. Conclusions.

The study is progressing fine after completion of institutional requirements following the Principal Investigator relocation from Morehouse School of Medicine in Atlanta to the University of Florida in Gainesville, Florida on July 1, 2002. The process of transferring the proposal and funding from Morehouse to UF has been completed. The final Army IRB approval is completed and the project is underway at the university of Florida. Also, the project is run through a sub-contract at Morehouse School of Medicine. The current IRB is valid up to August 2006. We anticipate by this date the study sample selection process would be completed.

VI. References.

Not Applicable.

VII. Appendices

Appendix A: Study of Prostate Cancer Screening and Mortality in Black and White Men In Five Atlanta Area SEER Counties Medical Record Abstracting of Cases Progress Report, January 2006

HOSPITALS	Number of Charts Reviewed	Charts Reviewed: Blacks	Charts Reviewed: Whites
V.A. M.C.	-	-	-
Crawford Long Hosp.	32	29	3
Dekalb Med Center	245	59	186
Emory University Hosp.	49	4	45
Grady H.S.	67	66	1
Piedmont Hospital	43	18	25
Total	436	176	260

BIOGRAPHICAL SKETCH

Dr. William Mkanta received his Bachelor of Science (Mathematics and Statistics) from the University of Dar es Salaam, Master of Statistics (Biostatistics) from Makerere University, Kampala, and PhD in health services research from the University of Florida. His research topic for the PhD degree was on the use of healthcare services among AIDS patients with long-term survival. Dr. Mkanta began his career at the Department of Statistics, University of Dar es Salaam, Tanzania, in April 1991 where he lectured in statistics and mathematics. In this position, Dr. Mkanta taught different statistical courses and also advised students taking economics and commerce. He also served as a statistical consultant for at the university as well as for governmental and non-governmental organizations. Dr. Mkanta has participated in various research projects within and outside Tanzania under different capacities such as statistical consultant, collaborating investigator, and principal investigator. His research interests include health services in HIV/AIDS, access and utilization of health care services, chronic disease, and health informatics. His most recent peer-reviewed publication on HIV/AIDS appeared in *AIDS Patient Care and STDs: Use of Health Care Services Among Persons Living with HIV Infection: State of the Science and Future Directions*, August 2005; 19(8): 473-485. Dr. Mkanta is currently working as a coordinator in Prostate Project at the Department of Health Services Research, Management and Policy, College of Public Health and Health Professions, University of Florida.

Nicole T. Scheys

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OBJECTIVE

To obtain research position that will utilize my public health knowledge and experience, outstanding communication and interpersonal skills, and strong work ethic.

EDUCATION

Masters of Public Health

May 2006

University of Florida, Gainesville, FL

Current GPA 3.85/ 4.0

Bachelor of Science in Food Science and Human Nutrition

May 2004

University of Florida, Gainesville, FL

Overall GPA 3.75/ 4.0

Science GPA 3.8/ 4.0

WORK EXPERIENCE

Research Assistant, UF Prostate Project

December 2005-present

Gainesville, FL

- Organized data using computer programs and abstracted data from medical charts
- Ran statistical analysis and prepared manuscripts

Student Assistant, Shands Dental Department

August 2001-December 2005

Gainesville, FL

- Performed secretarial tasks such as faxing, copying, organizing files, answered multi line phone
- Registered participants for classes, put class folders together
- Set up dental clinics, distributed dental instruments, provided refreshments, assisted instructors with classes

Research Assistant, UF Zoology Department

August 2003-July 2004

Gainesville, FL

Assisted research on three projects:

- Researched why cancer drug causes apoptosis in the heart muscle
- Tested and perfected new machine that measured oxygen consumption
- Maintained temperature and oxygen conditions of clam saltwater tanks and researched and ran assays on stress proteins

Cashier/Customer Service, Auntie Anne's Pretzels

August 1997-2002

Orlando, Florida

- Provided assistance to customers through interpersonal skills
- Performed fast and efficient on cash register, took orders, prepared and baked pretzels
- Assisted managers with all daily functions, occasionally filling in for a shift

VOLUNTEER WORK

Community Rounds

October 2004-present

Multidisciplinary, student-run organization providing health care and education to Gainesville's underserved communities

UF Project Mascot Tutor

Mentoring and tutoring at risk elementary aged children

4 semesters (2001-2004)

Volunteer at Shands Hospital @ UF

Pediatrics, NICU, Emergency Room

5 semesters (2001-2003)